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| 09/832,015 | 04/10/2001 | Nancy J. Woolf | NJW-1 | 9668 |

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GREENWALD & BASCH, LLP
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EAST ROCHESTER, NY 14445

EXAMINER

NICHOLS, CHRISTOPHER J

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1647

DATE MAILED: 01/24/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/832,015

Applicant(s)

WOOLF ET AL.

Examiner

Christopher Nichols, Ph.D.

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-9) drawn to a method of treating Alzheimer's disease comprising administering to a human patient an antagonist of a neurotransmitter receptor in Paper No. 3 (9 October 2002) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 10-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected material, there being no allowable generic or linking claim. Claims 1-9 will be examined to the extent that they read on a method of treating Alzheimer's disease comprising administering to a human patient an antagonist of a neurotransmitter receptor.

Status of Application, Amendments, and/or Claims

2. Claims 10-17 are withdrawn from consideration, as discussed above. Claims 1-9 are under examination.
3. To aid in correlating any papers for this application, all correspondence regarding this application should be directed to Art Unit 1647, Examiner Christopher Nichols.

Drawings

4. New corrected drawings are required in this application because the current drawings do not have correct margins nor are the drawings clear as to the invention or process depicted. Applicant is advised to employ the services of a competent patent draftsman outside the

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Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

6. The current abstract uses the legal phraseology "said". Appropriate correction is required.

7. The use of the trademarks "Exelon", "Cognex", and "Donepezil" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

8. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

9. Claim 1 is objected to because of the following informalities: "Alzheimer's" and "and" are misspelled, they should be "Alzheimer's" and "an" respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3, 4, 6, and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "specified level" in claim 3 is a relative term which renders the claim indefinite. The term "specified level" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the specification or the claims as to the metes and bounds of the term "specified level" are.

The term "peak level" in claim 4 is a relative term which renders the claim indefinite. The term "peak level" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the specification or the claims as to the metes and bounds of the term "peak level" are.

The term "additional amount" in claims 6 and 7 is a relative term which renders the claim indefinite. The term "additional amount" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear from the specification or the claims as to the metes and bounds of the term "additional amount" are.

11. Claims 5 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the concentrations of the antagonist and anticholinesterase are determined in the patient's brain, what controls are used, and what is measured in terms of units (presence or activity).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5668117 (16 September 1997) in view of US 5683422 (4 November 1997).

14. US 5668117 teaches the a process for treating Alzheimer's disease comprising administering two or more therapeutic agents (Col. 1 lines 20-55; Col. 2 lines 24-67). US 5668117 teaches a method of clinical treatment of Alzheimer's disease including the combination of a psychotherapeutic drug, such as haloperidol, and an acetylcholinesterase inhibitor, such as Cognex™, thus meeting the limitations of claim 1 (Col. 30-36 Example 2). Claim 1 requires the property of the neurotransmitter antagonist to indirectly inhibit phosphorylation of microtubule-associated protein-2 (MAP-2). While US 5668117 is silent with respect to this activity the specification suggests haloperidol as having this activity (pp. 3-6 and 8). Claim 2 adds further functional limitations, the specification suggests that haloperidol meets those limitations (pp. 3-6, 8, and 10). Thus, these activities are inherent to haloperidol taught by US 5668117. US 5668117 teaches co-use, which implies that haloperidol and Cognex™ could be administered simultaneously or one after the other (Example 2). Further, US 5668117 discusses the utility of administering drugs in certain combinations and varying dosages to improve drug retention ("supra-additivity") thus meeting the limitations of claims 3, 4, 6, and 7 (Col. 1 lines 45-55; Col. 15 lines 24-32; Col. 27 lines 63-67; Col. 28 lines 1-27).

15. US 5668117 does not teach the use of an implantable sensor to monitor the concentrations of the agents administered or the symptoms of Alzheimer's during the treatment regiment. US 6094598 teaches the use of an implantable sensor to monitor the course of drug

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treatment for neurological disorder. US 6094598 teaches a sensor which is capable of directly transducing the amount of a particular transmitter substance or its breakdown by-products found in the brain (Col. 5 lines 10-15). This implantable sensor is coupled to a conductor and a converter such that a person of ordinary skill in the art at the time of the invention could modulate the dosage of therapeutic agents delivered to the patient (Col. 5 lines 45-57).

16. It would have been obvious to a person of ordinary skill in the art at the time of the invention to use the combination of haloperidol and Cognex to treat Alzheimer's disease as taught by US 5668117 while monitoring the drug concentrations or effects of the drugs on neurotransmitters using the implantable sensor of US 6094598.

17. A person of ordinary skill in the art at the time of the invention would have been motivated to make these modifications as to better administer the two agents, the haloperidol and Cognex™ achieving and maintaining the appropriate dosages (Claim 4). Also US 5668117 discloses the additive effects of combinations of therapeutic drugs and US 6094598 teaches the advantages of monitoring drug levels at the site of desired effect (Col. 1 lines 1-55).

18. A person of ordinary skill in the art at the time of the invention would have expected success from these modifications because US 5668117 discloses the usefulness of co-agents to improve drug retention and dosages (Col. 1 lines 1-55), the drugs disclosed by US 5668117 were known to be effective, and the sensor of US 6094598 successfully monitored drug levels during therapy. Thus, the claimed invention as a whole was prima facie obvious over the combined teaching of the prior art.

Summary

19. Claims 1-9 are hereby rejected.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, PhD whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, PhD can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
January 13th, 2003

Elizabeth C. Kemmer

ELIZABETH KEMMER
PRIMARY EXAMINER